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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/030,884	10/25/2001	Emil M Orozco Jr	BB1355USPCT	6028

23906 7590 05/12/2004

E I DU PONT DE NEMOURS AND COMPANY
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WILMINGTON, DE 19805

EXAMINER	
BAUM, STUART F	

ART UNIT	PAPER NUMBER
1638	

DATE MAILED: 05/12/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/030,884	OROZCO JR ET AL.	
	Examiner	Art Unit	
	Stuart F. Baum	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 February 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *25-40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *25-40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *see office action* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *5/22/2003*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 25-40 are pending.

2. Applicant's election without traverse of Group I claims 1-9, 11-13, 17, 19, and 20-23, including SEQ ID NO:13 encoding SEQ ID NO:14 filed 2/5/2004 is acknowledged.

Claim 1-24 have been canceled.

3. Claim 25-40 have been newly added and are examined in the present office action.

Specification

4. Objection is made to the specification for not incorporating SEQ ID NO's when referring to nucleic acid or amino acid sequences. 37 CFR 1.821(d) requires the use of the assigned sequence identifier (e.g. SEQ I.D. NO: X) in all instances where the description or claims of a patent application discuss sequences.

Specification /Priority

5. Objection is made to the specification for improperly claiming the benefit of a provisional application. 37 CFR 1.78(a)(5)(i) requires that any nonprovisional application or international application designating the United States of America claiming the benefit of one or more prior-filed provisional applications must contain or be amended to contain a reference to each such prior-filed provisional application, identifying it by the provisional application number (consisting of series code and serial number). Amending the first paragraph of the specification to recite "This application is the National Stage of International Application No.

PCT/US00/12061, filed 5/3/2000, which claims the benefit under 35 U.S.C. § 119(e) of U.S. Provisional Application 60/133,040, filed May 7, 1999" will obviate this objection.

Inventorship

6. In view of the papers filed 2/5/2004, the inventorship in this nonprovisional application has been changed by the deletion of Zude Weng, Yong Tao, and Wesley B. Bruce.

The application will be forwarded to the Office of Initial Patent Examination (OIPE) for issuance of a corrected filing receipt, and correction of the file jacket and PTO PALM data to reflect the inventorship as corrected.

Drawings

7. The subject matter of this application admits of illustration by a drawing to facilitate understanding of the invention. Applicant is required to furnish a drawing under 37 CFR 1.81. No new matter may be introduced in the required drawing. It is noted that the International Application No. PCT/US00/12061 has drawings but a separate set of drawings are not included for the present Application.

Information Disclosure Statement

8. The information disclosure statement filed May 22, 2003 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered. The

Examiner could not locate a copy of the NCBI files. Applicant is requested to check the Identifier No. listed in each NCBI listing. For example, the Examiner was unable to open a file using the General Identifier No. 7489524 listed as Cite. No "CA".

Written Description

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 25-28 and 31-40 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to an isolated polynucleotide comprising a nucleotide sequence encoding an amino acid sequence exhibiting at least 80%, 85%, 90% or 95% sequence identity to SEQ ID NO:14, a vector, recombinant DNA construct, cell, plant or seed comprising said polynucleotide sequence, and method of selecting an isolated polynucleotide and method for positive selection of a transformed plant comprising said polynucleotide sequence.

Applicants disclose SEQ ID NO:13 encoding SEQ ID NO:14 (sequence lising).

The Applicants do not identify essential regions of the protein of SEQ ID NO:14 encoded by SEQ ID NO:13, nor do Applicants describe any polynucleotide sequences that

encode a polypeptide exhibiting 80% sequence identity to SEQ ID NO:14 that encode a functional protein of SEQ ID NO:14. The Federal Circuit has recently clarified the application of the written description requirement to inventions in the field of biotechnology. See University of California v. Eli Lilly and Co., 119 F.3d 1559, 1568, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). In summary, the court stated that a written description of an invention requires a precise definition, one that defines the structural features of the chemical genus that distinguishes it from other chemical structures. A definition by function does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is. The court goes on to say, "A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus." *See University of California v. Eli Lilly and Co.*, 119 F.3d 1559; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). Applicants fail to describe a representative number of polynucleotide sequences encoding a protein of SEQ ID NO:14 falling within the scope of the claimed genus of polynucleotides which encode a polypeptide exhibiting 80%, 85%, 90% or 95% sequence identity to SEQ ID NO:14. Applicants only describe a single cDNA of SEQ ID NO:13 encoding SEQ ID NO:14. Furthermore, Applicants fail to describe structural features common to members of the claimed genus of polynucleotides. Hence, Applicants fail to meet either prong of the two-prong test set forth by *Eli Lilly*. Furthermore, given the lack of description of the necessary elements essential for the protein of SEQ ID NO:14, it remains unclear what features identify a protein of SEQ ID NO:14. Since the genus of proteins of SEQ

ID NO:14 have not been described by specific structural features, the specification fails to provide an adequate written description to support the breath of the claims.

Enablement

10. Claims 25-40 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claimed invention is not supported by an enabling disclosure taking into account the *Wands* factors. *In re Wands,* 858/F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988). *In re Wands* lists a number of factors for determining whether or not undue experimentation would be required by one skilled in the art to make and/or use the invention. These factors are: the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples of the invention, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claim.

The claims are drawn to an isolated polynucleotide comprising a nucleotide sequence encoding an amino acid sequence exhibiting at least 80%, 85%, 90% or 95% sequence identity to SEQ ID NO:14, a vector, recombinant DNA construct, cell, plant or seed comprising said polynucleotide sequence, and method of selecting an isolated polynucleotide that affects the level of expression of a polypeptide in a plant cell and method for positive selection of a transformed plant comprising said polynucleotide sequence.

Applicants isolated their invention from a corn cDNA library (SEQ ID NO:13) and determined the function of the encoded protein (SEQ ID NO:14) to be an auxin transport protein using a homology based approach (page 31, lines 3 until page 32, line 3).

Applicants have not reduced to practice their invention. Applicants have only identified a cDNA encoding an auxin transport protein but Applicants have not taught or disclosed by way of example how one skilled in the art can use an auxin transport protein of SEQ ID NO:14 to alter the development of a plant. In regards to Applicant's SEQ ID NO:13, how and under what conditions should a nucleic acid encoding an auxin transport protein of SEQ ID NO:14 be used to control plant development? For example, how should the claimed invention be used to control root development, as stated by Applicant in the specification (page 2, lines 8-12? Does one skilled in the art want to increase the activity of the encoded polypeptide of SEQ ID NO:14 or decrease its activity in a plant? Furthermore, Applicants have not taught one skilled in the art, how to use a mutant plant in which the mutation has been complemented by overexpressing said polynucleotide. Applicants have simply produced a wild-type plant.

The state-of-the-art is such that one of skill in the art cannot predict which nucleic acids that encode a protein exhibiting 80%, 85%, 90% or 95% sequence identical to SEQ ID NO:14 will encode a protein with the same activity as a protein encoded by SEQ ID NO:14. The prediction of protein structure from sequence data and, in turn, utilizing predicted structural determinations to ascertain functional aspects of the protein, is extremely complex, and the positions within the protein's sequence where amino acid substitutions can be made with a reasonable expectation of maintaining function are limited (Bowie et al, Science 247:1306-1310, 1990, see especially page 1306). Proteins may be sensitive to alterations in even a single amino

acid in a sequence. For example, the replacement of a glycine residue located within the START domain of either the PHABULOSA or PHAVOLUTA protein receptor with either an alanine or aspartic acid residue, alters the sterol/lipid binding domain (McConnell et al, Nature 411 (6838):709-713, 2001, see especially page 710, left column, 2nd paragraph).

Applicants have not provided examples or guidance for selecting a sequence out of the multitude of sequences that are encompassed by Applicant's broad claim language, that gives the expected results when transformed into a plant. Transforming plants with heterologous genes that are involved in plant development produce unpredictable results. Kano-Murakami et al (1993, FEBS 334:365-368) teach introducing the *Oryza sativa* homeobox 1 (OSH1) gene into tobacco. OSH1 is a rice homologue of the *Knotted-1* homeobox gene from maize and would be encompassed by Applicant's broad claim language. Kano-Murakami et al teach transgenic tobacco plants comprising the OSH1 gene display a "range of phenotypes which include abnormalities in leaf and petal shape as well as stem height and number" (page 365, right column, 1st paragraph).

The state-of-the-art teaches transforming plants with nucleic acids encoding polypeptides involved in auxin sensitivity, perception or transport produce unexpected results. Benjamins et al (2001, Development 128:4057-4067) teach transforming Arabidopsis plants with a construct comprising the 35S promoter operably linked to the PINOID gene, which encodes a protein-serine/threonine kinase (abstract). "Seedlings of 35S::PINOID lines showed agravitropy and reduced elongation growth of roots and hypocotyls" (page 4061, right column, 1st full paragraph). Benjamins et al also report that lateral root formation was delayed and the main root meristem collapsed in a few days (*supra*).

In the absence of guidance, undue trial and error experimentation would be required for one of ordinary skill in the art to screen through the multitude of non-exemplified sequences, either by using non-disclosed fragments of SEQ ID NO:13 as probes or by designing primers to undisclosed regions of SEQ ID NO:14 and isolating or amplifying fragments, subcloning the fragments, producing expression vectors and transforming plants therewith, in order to identify those, if any, that when over-expressed produce plants with a desirable phenotype, which Applicants have not specified in the claims, and whose sequences fall within the scope of the claims.

Therefore, given the breadth of the claims; the lack of guidance and examples; the unpredictability in the art; and the state-of-the-art as discussed above, undue experimentation would be required to practice the claimed invention, and therefore the invention is not enabled.

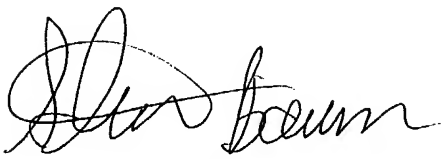
11. Claims 25-40 are deemed free of the prior art, given the failure of the prior art to teach or reasonably suggest an isolated polynucleotide of SEQ ID NO:13 encoding SEQ ID NO:14 and a method of selecting an isolated polynucleotide that affects the level of expression of a polypeptide in a plant cell and a method for positive selection of a transformed plant cell comprising said polynucleotide sequence.

12. No claims are allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stuart F. Baum whose telephone number is 571-272-0792. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on 571-272-0804. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.



Stuart F. Baum Ph.D.
Patent Examiner
Art Unit 1638
April 26, 2004